JUN 21 2010

K101080

510(k) Summary of Safety and Effectiveness

EGON FAULHABER
Surgical Instruments Pinzetten
Daimlerstr.1
D-78665 Frittlingen / Germany

Titel: Bipolar, Non Stick Bipolar and Monopolar Forceps

March 1, 2010

Submitter	EGON FAULHABER Surgical Instruments Pinzetten Daimlerstr.1 D-78665 Frittlingen Germany Karsten Faulhaber General Manager Telefon: +49 7426-7454 FAX: +49 7426-7266 E-mail: info@faulhaber-pinzetten.de
Application correspondent (cosultant)	Harald Jung General Manager JUNG Consulting Unterer Winkel 3 D-78573 Wurmlingen Germany Telefon +49 7461-96 92 36 FAX +49 7461-96 92 37 E-mail: hjung@harald-jung.de
Trade Name	EGON FAULHABER Bipolar Forceps, Non-Stick Bipolar Forceps and Monopolar Forceps
Common Name	Bipolar and Monopolar Forceps
Product Code and Classification Name	GEI, Electrosurgical Cutting and Coagulation and Accessories
Product Classification	21 CFR § 878.4400

K101080

Page 2 of 3

510(k) Summary of Safety and Effectiveness

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Predicate:

EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps are substantially equivalent to other legally marketed Bipolar and Monopolar Forceps from different manufacturers, e.g. Guenter Bissinger Medizintechnik GmbH, Sutter Medizintechnik GmbH, Kirwan surgical products - former: New England Surgical Instrument corp..

Device Description:

The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps are reusable devices and provided non sterile. They must be cleaned and sterilized before use.

Bipolar Forceps (see catalogue pages 08.01 – 08.09):
The branches are made of stainless steel insulated with Polyamide (PA) except for the tip of the instrument. The EGON FAULHABER Bipolar Forceps are of the same basic design with differences in tip sizes and handle styles. Two types of electrical plugs are available: flat plug, or 2 pin plug. The Bipolar Forceps are to be connected through a suitable bipolar cable with the bipolar output of an electrosurgical generator.
Bipolar Forceps must only be used with bipolar coagulation current.

Non-Stick Bipolar Forceps (see catalogue pages 07.01 – 07.09):
The Non-Stick Bipolar Forceps have the same characteristics as the Bipolar Forceps except for the special material with excellent thermal properties, applied to the tips of the forceps. Thereby difficult and time consuming cleaning of the forceps during an operation can be avoided and enables non-stop working. The non-stick effect is permanently ensured and will not be reduced, even if subject to frequent sterilization.

Monopolar Forceps (see catalogue pages 09.01 – 09.03):
The branches are made of stainless steel insulated with Polyamide (PA) except for the tip of the instrument. The EGON FAULHABER Monopolar Forceps are of the same basic design with differences in tip sizes and handle styles. They are available with or without plug socket. The Monopolar Forceps can be connected through a suitable monopolar cable with the monopolar output of an electrosurgical generator.
Monopolar Forceps must only be used with monopolar coagulation current.

K101080

Page 3 of (3)

510(k) Summary of Safety and Effectiveness

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Indications for Use

The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar and monopolar coagulation for general surgery where coagulation of soft tissue is needed. The bipolar forceps are used with the bipolar and the monopolar forceps with the monopolar output of standard electrosurgical generators. The EGON FAULHABER Bipolar and Monopolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

Intended Use

The types of surgery intended are:
General surgery, Laryngeal coagulation, Orthopedic coagulation, Thoracic coagulation, Neurosurgical coagulation, Gynecological coagulation (except for use in female sterilization), Urological coagulation, Ear-, Nose- and Throat coagulation.

Substantial Equivalence

The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps are substantial equivalent to the predicate devices, since the basic features, design and intended uses are the same. The minor differences between the EGON FAULHABER forceps and the predicate devices raise no new issues of safety and effectiveness, as these design differences have no effect on the performance, function or intended use of the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 21 2010

Egon Faulhaber Surgical Instruments Pinzetten
% Jung Consulting
Mr. Harald Jung
General Manger
Unterer Winkel 3
D-78573 Wurmlingen
Germany

Re: K101080
Trade/Device Name: Bipolar, Non-Stick Bipolar and Monopolar Forceps
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: March 29, 2010
Received: April 19, 2010

Dear Mr. Jung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101080

Device Name: **Bipolar, Non-Stick Bipolar and Monopolar Forceps**

Indications for Use:

The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps are intended for use by a physician familiar with electrosurgery in bipolar and monopolar coagulation for general surgery where coagulation of soft tissue is needed. The Bipolar Forceps are used with the bipolar, and the Monopolar Forceps are used with the monopolar output for standard electrosurgical generators.

The EGON FAULHABER Bipolar, Non-Stick Bipolar and Monopolar Forceps have not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

The types of surgery intended are:

General surgery, Laryngeal coagulation, Orthopedic coagulation, Thoracic coagulation, Neurosurgical coagulation, Gynecological coagulation (except for use in female sterilization), Urological coagulation, Ear-, Nose- and Throat coagulation.

Prescription Use YES (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use NO (21 CFR 801 Subpart C)

(PLEASE-DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Neil R.P. Ogden for mkm

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101080